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REMARKS

Claims 26-48 are pending in the application. Claims 26, 32, 39 and 46 have been amended to strike the outlining. Accordingly, no new matter is introduced by these amendments.

Reply to the Rejection of the Claims under 35 U.S.C. § 103(a)

Eskins in view of Van Soest, Fletcher and Goldemberg -

The Examiner has rejected claims 32-35, 39-42 and 46-48 as being unpatentable over U.S. Patent No. 5,676,994 to Eskins *et al.* ("Eskins") in view of U.S. Patent No. 6,340,527 to Van Soest ("Van Soest"), U.S. Patent No. 5,676,994 to Fletcher *et al.* ("Fletcher") or Robert L. Goldemberg, Society of Cosmetic Chemists, *Drug & Cosmetic Industry*, Vol., 159, No. 2, pp. 50-53 (New York, Aug. 1996) ("Goldemberg"). Specifically, the Examiner states –

Claimed invention is a surfactant-free aqueous composition comprising "cationic starch encapsulated hydrophobic material" containing an active ingredient. The starch encapsulated hydrophobic material is said to be non-separable.

Eskins teaches non-separable starch-oil compositions useful for food, agriculture, or pharmaceutical and cosmetic carriers or vehicles, which meets the "starch encapsulated hydrophobic material" limitation. See col. 13, lines 55-63; col. 11, lines 60-66; instant claims 32, 39, 46. The abstract teaches that the composition is prepared in the absence of external emulsifying or dispersing agents. The reference teaches "the presence of the oil component in [the starch-oil-water] composition causes them to function as emulsifying and dispersing agents and makes them receptive to the addition of a variety of water-immiscible materials, for example, additional lipid, volatile, and essential oils and food flavoring materials, antioxidants, medicinal agents, agricultural chemicals". See col. 5, lines 40-53. The application of the starch-encapsulated actives in cosmetic formulations includes body and hand lotions, cream, and suntan lotion. Examples also illustrate encapsulating soybean oil. See instant claims 39 and 47. Example 13 teaches a dispersion of 300 g of soybean oil in 3 liters of water, which constitutes 10 % by weight. See instant claims 35, and 42. The method of topically applying the topical composition is an obvious use of the composition. See instant claims 46-48.

It is noted that claims 34, 41 and 48 are product-by-process claims, where only the limitation to the composition itself is given patentable weight. See MPEP § 2113. Eskins nonetheless teaches that the invention is prepared by jet cooking the starch. See col. 8, line 64 – col. 13, line 21.

Eskins fails to teach cationic starch.

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Van Soest teaches that cationic starch is well known encapsulating material for hydrophobic or water insoluble solid active ingredients. See col. 1, line 36 – col. 2, line 11.

Fletcher et al. teach viscous antiperspirant aqueous emulsions comprising amphoteric or cationic modified starch. See abstract; col. 1, line 7 – col. 35; col. 7, lines 6-30. The reference teaches that the compositions exhibit excellent phase stability even in the high concentrated antiperspirant salts in the solution and elevated storage temperature. See col. 2, line 53 – col. 19, line 22.

Goldemberg teaches that it is well known in cosmetic art to employ cationic modified starch to entrap and stabilize antioxidants in a cosmetic composition. See page 2, 6th full par.

Given the teaching of starch encapsulants for cosmetic ingredients in Eskins, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have looked to the prior arts such as an Soest, Fletcher, and Goldemberg for specific type of starch and used cationic starch as motivated by the teachings of these references because of the expectation of successfully producing a stable cosmetic composition. . . .

. . . . Applicant's arguments are generally directed to the deficiencies of each reference. It is respectfully pointed out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cr. 1986).

Applicants assert that the teachings of Eskins is limited to "unmodified starch". The reference in fact teaches, "modified starches may be used, however, to prepare compositions of this invention, if certain properties are desired that are not obtainable with unmodified starches". See Eskins, col. 6, lines 31-41. Thus the emulsifier-free emulsion of Eskins also uses modified starches. The reference also states, "modified starch does not have the sticky, gummy properties of unmodified starch and also functions as an emulsion stabilizer". See Eskins col. 3, lines 55-65 (referring to the Hermansson patent). Thus it is well known in the art that emulsifier-free emulsion can be made with modified starch, as applicants have done in the present case.

The presence of surfactants in the Van Soest composition does not negate the teaching of the Eskins that modified starches stabilize emulsifier-free emulsion. While applicants argue that Van Soest invention is limited to using granular type of starch, examiner notes that the claims do not distinguish whether the starch is granular or non-granular. If the starch produced by jet cooking necessarily is non-granular type, it must be noted that the inventions in Claims 26, 28-47 do not require non-granular type of starches. Nowhere in the Van Soest indicates that granular type of starches is the only starch suitable for the invention. Furthermore, using modified starches produced by jet steam cooking is well known in the art, as evidenced by Eskins.

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Applicants assert that Fletcher is not combinable with Eskins and Van Soest because former allegedly fails to teach aqueous formulation. The arguments are not persuasive as the Fletcher reference in fact teaches that the cationic modified starch is added in the aqueous phase of the emulsion to form a viscous [*sic*, viscous] emulsion. See abstract.

Applicants further argues that the prior art is limited to using hydrophilic active ingredients and that the prior art uses surfactants in the composition. Applicants make analogous arguments against applying Goldemberg. In response, examiner reiterates that it is Eskins which provides the teaching that modified starches can stabilize emulsion without the aid of emulsifiers. Encapsulating hydrophobic active compounds with modified starches is also taught by the primary reference.

While applicants assert that the rejection is a hindsight reconstruction made with numerous references, examiner respectfully points out that reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, all the evidence used to make the necessary motivation to combine the references are taught in the references. Examiner asserts that no impermissible hindsight was used to make the rejections.

For the following reasons, Applicants respectfully traverse the Examiner's rejection of claims 32-35, 39-42 and 46-48 as being unpatentable over Eskins in view of Van Soest, Fletcher and Goldemberg.

Eskins discloses a process for preparing stable and non-separable compositions of starch and oil without the use of external emulsifying or dispersing agents (Abstract; col. 5, lines 21-25). These compositions are prepared by gelatinizing (cooking) starch in the presence of water under conditions that completely solubilize the starch, and then mixing the oil in the starch/water solution under conditions of high turbulence before the starch can retrograde (col. 5, lines 25-29; col. 7, line 60 -- col. 10, line 28). The products of Eskins are recovered under conditions that stabilize the distribution of the oil in the starch phase, *i.e.*, allowing the emulsion to cool below 100°C or lower prior to drying (col. 9, lines 54-64). Once cooled, the starch/oil/water dispersion can optionally be dried (col. 11, lines 7-9). Preferably, drum drying is used to dry the dispersion

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(col. 11, lines 11-13), although other drying techniques can be use as long as the cooked dispersion is allowed to cool below 100°C while still in the form of a fluid aqueous dispersion (col. 11, lines 21-27).

The compositions of Eskins are preferably prepared from unmodified starch (*i.e.*, one that has not be altered by chemical treatment or reduced in molecular weight (degraded) by reaction with acids or enzymes (col. 6, lines 26-28)), although modified starch can be used (col. 6, lines 17-20 and 31-34). Eskins provides no guidelines as to what types of chemically modified or degraded starches can be used or whether further modification to the process is required when such a modified starch is employed (*e.g.*, addition of a surfactant), and only exemplifies unmodified starches. The 'oil' of Eskins interchangeably refers to lipids, fats and oil, with vegetable oils, animal fats and mineral oils preferred (col. 7, lines 1-14).

Eskins teaches that its compositions are suitable for use in food formulations (col. 11, lines 46-59; col. 12, lines 5-14). Eskins further suggests that its compositions are useful as carriers for pharmaceutical, cosmetic and personal care formulations such as sun tan lotions, as well as carriers for agricultural actives; however, Eskins provides no exemplification of such applications (col. 11, line 60 – col. 12, line 5 and 15-20).

Eskins is cited in the 'Background' and 'Detailed Description' portion of the present description as disclosing a process for preparing stable, water-insoluble starch-oil compositions formed by jet cooking a mixture of starch and other ingredients.

Van Soest teaches another process for encapsulating active ingredients in a crosslinked starch shell (Abstract). According to the process of Van Soest, oil or another hydrophobic substance is added to an aqueous solution or dispersion of starch (col. 2, lines 52-54). If the active ingredient is also hydrophobic, it can be added with the oil (col. 1, lines 36-51; col. 2, lines 58-59). Preferably, a surfactant is added to the aqueous dispersion before the hydrophobic substance is added (col. 2, lines 61-63). Crosslinking is brought about by the addition of a crosslinking agent to the aqueous dispersion of starch (col. 3, lines 33-35).

Once a stable oil-in-water emulsion is achieved, it is dispersed in a hydrophobic ('oil') phase, thereby forming an oil-in-water-in-oil emulsion (col. 3, lines 6-14). Another surfactant can be added to this second phase for promoting the water-in-oil emulsion (col. 3, lines 14-16). Crosslinking can occur at any desired point in the process, preferably after formation of the oil-

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in-water-in-oil emulsion, by addition of a catalyst or raising the temperature of the emulsion (col. 3, lines 35-41).

“Suitable starches are native starch and fractions and derivatives thereof. Preferably, the starch is a granular starch” (col. 1, lines 55-58). Starch derivatives refer to modified granular starches and include oxidized starch, carboxyalkylated starch, sulfated or phosphated (cationic) starch (col. 1, line 59 – col. 2, line 11). Further, it is well known in the art to crosslink starch granules so that they are only partially or completely insoluble in water, solubility being controlled based upon the degree of crosslinking. Such crosslinked starch granules are typically used in the art as thickeners. According to Van Soest, the use of granular starches has advantages over soluble starches, including the degree of gelatinization (*i.e.*, thickening) (col. 2, lines 12-32).

The Examiner cites Van Soest as teaching the use of cationic starch as encapsulating material for hydrophobic or water insoluble solid active ingredients. However, as shown above, Van Soest more accurately teaches the use of crosslinked, cationic starch granules for use as encapsulating material. Contrary to Eskins, Van Soest does not teach cooking out the starch. Instead, Van Soest teaches the opposite of Eskins – that granular starches are preferred for use as encapsulating material. Accordingly, one skilled in the art would not look to Van Soest and its crosslinked, cationic starch granules as being useful or desirable as the cooked-out starch constituent of Eskins. Therefore, the Examiner’s combination of Eskins with Van Soest is improper. Further, as the crosslinked, modified starch granules of Van Soest tend to be non- or only partially water soluble, and Eskins teaches fully solubilized starch as being preferred, one skilled in the art would believe that a surfactant as taught by Van Soest would also be required in the process of Eskins were the cationic starch granules of Van Soest used in the process of Eskins (for promoting the formation of the oil-in-water emulsion). (It should be noted again that Eskins prefers the use of unmodified starch, and provides no guidelines as to how modified starches can be applied in its process).

Fletcher teaches antiperspirant compositions formed from a dispersion of a hydratable polymer such as a cationic starch in an aqueous emulsion that is subjected to high shear, agitating the emulsion, and introducing an antiperspirant salt into the emulsion to form the inventive antiperspirant emulsion (Abstract; col. 2, lines 52-67). The emulsion is formed from an aqueous

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phase and an oil phase with an emulsifier in at least one of the two phases (col. 5, lines 38-40). The starch is added to thicken the emulsion, with the amount of starch added varying based on particular application (col. 8, lines 10-24; *see also*, col. 3, lines 20-44; col. 5, lines 9-15). Fletcher does not teach or suggest starch encapsulation, nor does it teach or suggest the use of its cationically modified granular starches as an encapsulating material. Rather, Fletcher is directed towards the formation of stable oil-in-water emulsions that remain stable when a hydrophilic salt is added to the emulsion. Accordingly, one skilled in the art would not look to the cationic granular, thickening starch of Fletcher as being useful as a cooked-out modified starch in the process of Eskins.

The Examiner misquotes Goldemberg in stating that it “teaches that it is well known in cosmetic art to employ cationic modified starch to entrap and stabilize antioxidants in a cosmetic composition”. As previously stated, Goldemberg discloses entrapment of free radical scavengers in glycospheres having a cationically modified starch core. The scavengers are anionic hydrophilic constituents (here, extracts of the polyphenols nutgall and green tea) that are entrapped or retained on the core. (It is believed that this entrapment is due to ionic bonding.) Goldemberg does not teach or suggest starch encapsulation of a hydrophobic material; rather, Goldemberg teaches glycospheres having a polysaccharide core or center. Recognizing that Goldemberg only teaches entrapment of hydrophilic materials as opposed to hydrophobic materials, and further does not teach starch encapsulation of a hydrophobic material, one skilled in the art would not consider the cationically modified starch cores of Goldemberg suitable for use in the starch/oil/water dispersion of Eskins.

As stated by the Examiner, Eskins fails to teach cationic starch. While Van Soest, Fletcher and Goldemberg teach cationically modified starch, as shown above none of the references provide one skilled in the art with the motivation to cook out (*i.e.*, completely gelatinize) that cationic starch in a starch/water/hydrophobic mixture obtain a starch-encapsulated hydrophobic material for use in a personal care or cosmetic formulation. Only Van Soest teaches starch encapsulation. Van Soest does not teach solubilizing (cooking out) its starch for use in encapsulation. Further, Van Soest uses a surfactant to stabilize its formulations. Accordingly, one skilled in the art is provided with no teaching or suggestion that the cationic

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starch granular of Van Soest would be suitable for use when cooked out and would provide stability without the use of added surfactants.

It is well recognized that statements that modifications of the prior art to meet the claimed invention would have been well within the ordinary skill of the art at the time the claimed invention was made because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.). As shown above, there is no objective reason for combining the cited references.

For at least these reasons, claims 32-35, 39-42 and 46-48 are patentable over Eskins in view of Van Soest, Fletcher and Goldemberg. Withdrawal, therefore, of the rejection of claims 32-35, 39-42 and 46-48 under 35 U.S.C. § 103(a) is respectfully requested.

Eskins in view of Van Soest, Fletcher and Goldemberg and further in view of Macaulay -

The Examiner has rejected claims 26-28 as being unpatentable over Eskins in view of Van Soest, Fletcher and Goldemberg as applied to claims 32-35, 39-42 and 46-48 above, and further in view of U.S. Patent No. 6,362,146 to Macaulay ("Macaulay"). Specifically, the Examiner states –

The combined references fail to teach sunscreen active ingredients.

Macaulay teaches that encapsulated sunscreens are known in the art. See col. 6, lines 4-25. The reference further teaches a water-based cleansing composition comprising 2, 5, and 10% of the encapsulated sunscreen actives. See Example 1; instant claims 27 and 42.

Given the teaching of the cosmetic application of the starch-encapsulated active ingredients in Eskins, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added sunscreen actives in the active ingredients as motivated by Macaulay, because of the expectation of successfully producing controlled-release sunscreen compositions.

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For the following reasons, Applicants respectfully traverse the Examiner's rejection of claims 26-28 as being unpatentable over Eskins in view of Van Soest, Fletcher and Goldemberg as applied to claims 32-35, 39-42 and 46-48 above, and further in view of Macaulay.

Eskins, Van Soest, Fletcher and Goldemberg were previously discussed, those arguments being incorporated herein.

Macaulay is cited by the Examiner for its teaching of the encapsulation of sunscreen actives. Macaulay teaches personal washing compositions that include a surfactant, a polymeric deposition aid, and an encapsulated sunscreen (Abstract). According to Macaulay, the encapsulated sunscreen is a combination of an organic sunscreen active that is trapped within a wax or oil matrix (col. 6, lines 4-18). The encapsulant is supplied as an emulsion in an aqueous or oil carrier, depending upon the nature of the sunscreen active (col. 6, lines 18-25).

Macaulay does not teach or suggest starch encapsulation of its sunscreen actives. Further, as Macaulay recognizes that the nature of the active can affect the emulsion, it cannot objectively be said that sunscreen actives per se can be starch encapsulated based upon the teachings of Macaulay. Accordingly, one skilled in the art would not be motivated to look to Macaulay for sunscreen actives to be encapsulated in a cationically modified starch granule according to Van Soest for application in Eskins.

For at least these reasons, claims 26-28 are patentable over Eskins in view of Van Soest, Fletcher and Goldemberg as applied to claims 32-35, 39-42 and 46-48 above, and further in view of Macaulay. Withdrawal, therefore, of the rejection of claims 26-28 under 35 U.S.C. § 103(a) is respectfully requested.

Eskins in view of Van Soest, Fletcher, Goldemberg and Macaulay and further in view of Ashley -

The Examiner has rejected claims 29-31, 36-38 and 43-45 as being unpatentable over Eskins in view of Van Soest, Fletcher, Goldemberg and Macaulay as applied to claims 26-28, 39-42 and 46-48 above, and further in view of the publication Ashley, *Sunburn and Sunscreen Preparations*, Poucher's Perfumes, Cosmetics and Soaps ("Ashley"). Specifically, the Examiner states -

The combined references fail to teach the water content in the cosmetic compositions as required by the instant claims.

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Ashley teaches various formulations for sunscreen and suntan preparation. See p. 434 – p. 437. Formula 4 and 6 shows cream compositions having about 40 and 20 % of water by weight, respectively.

While there is no explicit teaching of using only 10 % of water as in instant claims 29 and 43, it must be noted that differences in concentration generally will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Ashley, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation.

For the following reasons, Applicants respectfully traverse the Examiner's rejection of claims 29-31, 36-38 and 43-45 as being unpatentable over Eskins in view of Van Soest, Fletcher, Goldemberg and Macaulay as applied to claims 26-28, 39-42 and 46-48 above, and further in view of Ashley.

Eskins, Van Soest, Fletcher, Goldemberg and Macaulay were previously discussed, those arguments being incorporated herein.

Ashley teaches oil/water and water/oil emulsions in the form of creams and lotions. These compositions require emulsifiers or surfactants for particle stability. In contrast, the claimed personal care formulations of the present invention do not contain surfactants, which can result in irritation and allergic reactions. Ashley is cited by the Examiner for teaching the water content in cosmetic compositions and for no other reason. Accordingly, Ashley does not remedy the deficiencies of the other references. Further, one skilled in the art would not combine Ashley which requires emulsifiers or surfactants to result in the presently claimed surfactant-free composition.

For at least these reasons, claims 29-31, 36-38 and 43-45 are patentable over Eskins in view of Van Soest, Fletcher, Goldemberg and Macaulay as applied to claims 26-28, 39-42 and 46-48 above, and further in view of Ashley. Withdrawal, therefore, of the rejection of claims 29-31, 36-38 and 43-45 under 35 U.S.C. § 103(a) is respectfully requested


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It is believed that the above amendments and remarks overcome the various rejections of the claims. Allowance of the claims is believed to be in order, and such allowance is respectfully requested.

Respectfully submitted,

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